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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/538,832

06/13/2005

Pia Norup Nielsen

P68468US1

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136 7590 12/05/2008

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EXAMINER

ANDERSON, CATHARINE L

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

12/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/538,832 | Applicant(s) NIELSEN, PIA NORUP | |
| | Examiner Lynne Anderson | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8, 10-22, 24, 25 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8, 10-22, 24, 25 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 October 2008 has been entered.

Response to Arguments

2. Applicant's arguments filed 17 October 2008 have been fully considered but they are not persuasive.

3. In response to applicant's argument that the catheter of Nilsson is designed to be an indwelling catheter, not an intermittent catheter, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While the catheter of Nilsson is designed for indwelling use, it is still fully capable of being removed and re-inserted, and therefore meets the claimed limitations.

4. In response to the applicant's argument that the limitation "adapted for intermittent catheterization" is not intended use, it is noted that the claimed limitation does not provide any structural features that distinguish an indwelling catheter from an

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intermittent catheter. Therefore, the limitation "adapted for intermittent catheterization" is considered to disclose an intended use for the catheter.

5. In response to the applicant's argument that Nilsson fails to disclose a hydrophilic polymer coating, it is noted that Hunter is relied upon for the teaching of a hydrophilic polymer coating comprising a pharmaceutically active agent. Hunter describes on page 2, lines 22-23, a catheter provided with a hydrophilic surface coat, and on page 3 discloses pharmaceutically active agents comprised in the coating. Hunter further discloses on page 4, lines 17-18, the use of a hydrophilic polymer coating. The teachings of the pharmaceutically active agent being a hormone or an efferent blocking agent are provided by Martan and Ottoboni, respectively.

6. In response to the applicant's argument that Ottoboni does not teach treatment of incontinence by delivery of oxybutinin to the lower urinary tract by the urethra, it is noted that Ottoboni is not relied upon for the teaching of delivery of a pharmaceutically active agent by the urethra. Ottoboni is relied upon only for the teaching of oxybutinin as a pharmaceutically active agent for internal deliver for the treatment of incontinence. It is Nilsson that is relied upon for the teaching of delivering a pharmaceutically active agent to the lower urinary tract by the urethra.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 8, 10-14, 21-22, 24-25, and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson (WO 91/00074) in view of Hunter (WO 02/24246).

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9. With respect to claims 8, 10, 14, and 27-29, Nilsson discloses all aspects of the claimed invention with the exception of the pharmaceutically active composition being located on the outer surface of the catheter. Nilsson discloses a device comprising a urinary catheter element 10, as shown in figure 1. The catheter element 10 is fully capable of being removed and reinserted, and therefore is adapted for intermittent catheterization. The catheter 10 has a pharmaceutically active composition comprising a hormone disposed therein, as disclosed on page 8, lines 3-8. The pharmaceutically active composition is delivered to the urinary tract during catheterization, as disclosed on page 8, lines 9-16.

10. Hunter teaches the application of a pharmaceutically active composition on the outer surface of a urinary catheter, as disclosed on page 2, lines 23-24. The pharmaceutically active agent is applied to the catheter by means of a hydrophilic polymeric coating, as described on page 4, lines 17-18.

11. It would have been obvious to one of ordinary skill in the art at the time of invention to provide the pharmaceutically active composition in a hydrophilic polymeric coating on the outer surface of the urinary catheter of Nilsson, since Hunter teaches the predictable result of a pharmaceutically active composition being delivered to the user when the composition is coated on the surface of the catheter.

12. With respect to claim 11, Nilsson discloses depressions 15 on the outer surface, as shown in figure 1, which are adapted to hold the pharmaceutically active agent, as described on page 8, lines 3-8.

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13. With respect to claims 12 and 13, Hunter discloses the coating is a lubricating gel, as described on page 2, lines 9-10.

14. With respect to claims 21-22 and 24-25, Nilsson discloses the use of the device to perform the method of treating a female suffering from incontinence, as disclosed on page 1, lines 5-29.

15. Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson (WO 91/00074) in view of Hunter (WO 02/24246), and further in view of Martan et al. ("Ultrasound imaging...", Ceska Gynekol, Jan. 1999).

16. Nilsson, as modified by Hunter, discloses all aspects of the claimed invention with the exception of the hormone being oestriol or oestrogen. Martan teaches the use of oestriol and oestrogen in the treatment of females suffering from incontinence (see Abstract). The oestriol or oestrogen is administered intravaginally. It would therefore be obvious to one of ordinary skill in the art at the time of invention to use oestriol or oestrogen as the hormone in the device of Nilsson, as taught by Martan, to effectively treat incontinence.

17. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson (WO 91/00074) in view of Hunter (WO 02/24246), and further in view of Ottoboni et al. (6,039,967).

18. Nilsson, as modified by Hunter, discloses all aspects of the claimed invention with the exception of the pharmaceutically active composition being an efferent blocking

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agent comprising oxybutynin. Ottoboni teaches the use of oxybutynin in the treatment of incontinence, as disclosed in column 5, lines 14-16. The oxybutynin is delivered to the urinary tract by a catheter coated with the composition, as disclosed in column 7, Example 7. It would therefore be obvious to one of ordinary skill in the art at the time of invention to use oxybutynin as the pharmaceutically active composition of Nilsson, as taught by Ottoboni, to effectively treat incontinence.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynne Anderson whose telephone number is (571)272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. A./

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761